UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/428,458	10/28/1999	KJETIL TASKEN	Q-56244	4681

7590 02/11/2004

SUGHRUE MION ZINN MACPEAK & SEAS PLLC
2100 PENNSYLVANIA AVENUE N W
WASHINGTON, DC 200373202

EXAMINER	
LACOURCIERE, KAREN A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/428,458	TASKEN ET AL.	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-45, 47-49 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-45,47-49 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Applicant requested and interview summary indicating that the priority documents were received, however, the Examiner in the instant case has changed, no interview summary appears in the case and, therefore, the interview summary cannot be provided.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Specifically, changes have been made in the date section of the signature of inventor Muller, but these changes have not been initialed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Gjertsen et al. for the reasons of record set forth in the prior Office action mailed 05-06-2003.

Response to Arguments

Applicant's arguments filed November 6, 2003 have been fully considered but they are not persuasive. In response to the rejection of record of claims 40-42 as anticipated by Gjersten et al., Applicant argues that the compositions disclosed by Gjersten et al. are not pharmaceutical compositions because the only use set forth by Gjersten et al. for their compositions were in vitro uses. Applicant argues that a pharmaceutical composition, as claimed, must be suitable for use in a clinical setting. Applicant further argues that the compounds used to make the compositions disclosed in Gjersten et al. were purchased from BIOLOG Life Sciences and that they have provided a declaration from the company that indicates that the compounds supplied to

investigators, including for example, the compounds used in Gjertsen et al., were supplied as pure chemicals, may contain trace amounts of impurities and are not produced under GMP conditions and, therefore, are not suitable for pharmaceutical use and contain no filler or buffer (declaration of Hans-Gottfried Gonieger, filed June 19, 2002) Applicant argues that the compositions used in the instant Application have been treated to make them suitable for use as a pharmaceutical, whereas the compositions of Gjersten et al. were not.

These arguments have not been found to be persuasive because a different use for a known composition does not confer patentability to the composition. Applicant argues limitations, including endotoxin free and produced in a GMP setting, which are not limitations in the claims, nor are they treatment steps disclosed in the specification. The compositions disclosed by Gjersten et al. meet all of the limitations of the claimed compositions and can be used for pharmaceutical purposes, as evidenced by Punch et al. Punch et al. is a post-filing reference, but provides evidence that the compositions disclosed by Gjersten et al. are suitable for use pharmaceutically, in a clinical setting, for example, in rats. Punch et al. disclose using compounds disclosed by Gjersten et al. and purchased by BIOLOG Lifesciences (see for example, page 8521, which indicates compounds used by Gjersten et al. and the material and methods section which indicates the source of the compounds was BIOLOG Life Sciences, Bremen, Germany) with the only additional treatment being addition of phosphate buffered saline. The additional steps set forth in Applicant's arguments (e.g. endotoxin removal, preparation in a GMP setting) were not required, as the clinical experiments were performed on rats.

It is noted, Punch et al do not use the same analogues instantly claimed, but other analogues used in Gjersten et al. and supplied by BIOLOG life Sciences in the same form as the claimed analogues were supplied to Gjersten et al. Punch et al. illustrates that cAMPS compounds in the form supplied by BIOLOG Lifesciences, as disclosed by Gjersten et al., are actually suitable for use in vivo.

The declaration under 37 CFR 1.132 filed June 19, 2002 has been considered, but is insufficient to overcome the rejection of claims 40-42 based upon Gjersten et al. as set forth in the last Office action because: Although the opinion of Mr. Hans-Gottfried Gonieger is that the cAMPS compounds supplied by BIOLOG Life Sciences are not suitable for in vivo use and are not pharmaceutical, this opinion is not universally held. For example, although the cAMPS compounds supplied by BIOLOG Life Sciences may not be appropriate for use in a clinical setting in a human, this same standard does not apply for in vivo use in animal studies, which is also encompassed within the scope of "pharmaceutical". Additionally, the declaration of Hans-Gottfried Gonieger appears to comment on the state of the compounds as shipped by the supplier, indicating that no filler or buffer was added and that the compounds were lyophilized, however, the claims are rejected as provided in the Gjersten et al. reference. Gjersten et al. further treated the supplied cAMPS analogues by adding a buffer and filler, as required by the instant claims.

Claims 40-44 are maintained as rejected under 35 U.S.C. 102(e) as being anticipated by Cho-Chung et al. (US Patent 5,843,916) for the reasons of record set forth in the prior Office action, mailed 05-06-2003.

Response to Arguments

Applicant's arguments filed November 6, 2003 have been fully considered but they are not persuasive. In response to the rejection of record of claims 40-44 under 35 USC 102(e) as anticipated by Cho-Chung et al. Applicant argues that Cho-Chung et al. discloses generally phosphorothioate derivatives of 8-halo-cAMP, including all cAMPS compounds, (phosphorothioate and phosphorodithioates) and an 8-substituted halogen. Applicant argues that this general disclosure constitutes a large genus, of 15 compounds, and the genus is not inherently limited to a small number of compounds and, therefore, the specific compounds claimed are not disclosed in Cho-Chung et al.

This argument is not found to be persuasive because Cho-Chung et al. specifically discloses prefereably phosphorothioate derivatives of 8-Br-cAMPS, which constitutes a genus of only two compounds, Sp-8-Br-cAMPS and Rp-8-Br-cAMPS, which is inherently a very small number of compounds. Even if the genus were extended to include phosphorodithioate derivatives, as suggested by Applicant, that genus is also very small and would only add two more compounds (4 compounds total), which is also inherently a very small number of species. Therefore, Cho-Chung et al. anticipates claims 40-44.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-45 and 47-49 are maintained as rejected and new claim 51 is rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the prior Office action, mailed 05-06-2003.

Response to Arguments

Applicant's arguments filed 11-06-2003 have been fully considered but they are not persuasive. In response to the rejection of record under 35 U.S.C. 112, first paragraph, Applicant argues that Gjersten et al. does not support the assertion that the antiagonists of the claimed invention are unpredictable. Applicant further argues that all compounds do not need to be tested to meet that standard for enablement. Applicant argues that they have demonstrated efficacy for a significant number of the claimed compounds and that each of the claimed compounds has been shown to have some efficacy in vitro.

These arguments have not been found to be persuasive. Gjersten et al. demonstrates the various compounds of the claimed methods have unexpected different abilities to inhibit the target enzyme. Given this difference in efficacy, it would be unpredictable that each of the compounds as claimed would be as efficacious in

vivo, as required by the claimed methods, and it is unpredictable that they would achieve the degree of inhibition required to provide the treatment effects required by the claimed methods. Further, although applicant has demonstrated inhibition in vitro, it is unclear that this would correlate with efficacy in vivo, to result in a treatment effect for the broad range of diseases encompassed in the claims. Applicant's arguments do not address the scope of the claimed invention. Therefore, the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (571) 272-0759. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Lacourciere
February 9, 2004

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER